Recommendation 1: Transfusion Related Acute Lung Injury (TRALI)

The Committee reviewed the transfusion related acute lung injury (TRALI) data and did not find scientific evidence to recommend an intervention at this time. The Committee recommends that the Secretary support:

- the expeditious development of a standardized definition,
- implementation of clinician education and effective surveillance,
- modeling the impact of deferral or screening intervention, and
- research into the etiology, diagnostic testing, epidemiology, treatment and prevention.

Voting:
16 in favor (August 26, 2004)
0 against
Amended on August 27, 2004 to remove "available," "sufficient," and "specific"
9 in favor
0 against
1 abstention

Recommendation 2: Access to Treatment for Individuals with Rare Blood Disorders

Whereas, the Department of Health and Human Services' (DHHS) Advisory Committee on Blood Safety and Availability recognizes the lack of licensed treatments for individuals with rare blood disorders (e.g. Factors V, VII, XI, XIII and Protein C deficiencies) presents a significant health risk and a discrepant therapeutic standard from that for persons with some other blood disorders such as hemophilia; and,

The Committee notes importation for personal use and off-label use are not adequate long-term solutions or acceptable alternatives; and,

The Committee concurs that there is a need to promote the development and licensure of treatment products for these individuals; and,

It may be appropriate to adopt flexible approaches to validating therapies for rare blood disorders.

The Committee recommends that DHHS promote the development of products to treat individuals with rare blood disorders including facilitating:

1. Obtaining additional licensed indications for already licensed products; and,
2. Approval of products and their indications in the United States for European licensed products; and,
3. Developing new products.

The Committee also recognizes the importance for industry, investigators and regulators to cooperate in both pre and post market approval of potential new therapies and indications.

The Committee encourages the government to invest in research and to support adequate reimbursement to optimize treatment for rare blood disorders.

Voting on August 27:
16 in favor
0 against
1 abstention

Recommendation 3: Bacterial Detection in Platelet Concentrates and Seven Day Platelets

Whereas;

-Consistent with previous recommendations of the Committee, the Advisory Committee on Blood Safety and Availability has concluded that bacterial contamination of room temperature stored platelet components represents one of the most significant remaining infectious risks of blood transfusion; and,

-The transfusion medicine community has adopted a voluntary standard that requires the implementation of methods to limit and detect bacterial contamination in all platelet components; and,

-There is now inconsistent practice in the application of currently available bacterial screening tests and the Committee recognizes that public health would be improved by the availability of a release test approved for this purpose; and,

- Given the current inadequate supply of platelets, the Committee recognizes the need for seven day storage of platelets to meet patient needs; and,

- The currently proposed study of bacterial screening for release control of 7-day stored platelets would take at least two years to complete.

The Committee recommends to the Secretary of Department of Health and Human Services that:

- The Department support the use of grant or contract funding that would allow availability of funds to support applications to develop bacterial screening suitable for release testing of platelets for use in routine practice.

-The Department consider alternative strategies that could expedite licensure of seven day platelets in significantly less than two years.

Whereas, the Committee has heard evidence that:

1) most apheresis platelets are currently tested by an approved quality control method to detect contamination by bacteria,
2) individual whole blood derived platelets (WBDP) are not and can not be similarly tested by a practical validated assay for bacterial contamination,
3) this situation has resulted in a dual level of safety for platelets prepared for transfusion, and
4) a threat to platelet supply has developed as the inventory of WBDP declines.

Given the availability of;

1) in vitro data supporting the acceptable quality of pre-storage pooled WBDP
2) European data supporting the clinical safety and efficacy of pre-storage pooled whole blood derived buffy coat platelets
3) the data from the McMaster study of the clinical safety and efficacy of pre-storage pooled WBDP,

The Committee urges Department of Health and Human Services to adopt strategies to expedite licensure of a pre-storage pooled WBDP component for transfusion based on a critical review of the available information.

Voting on August 27:
15 in favor
0 against
2 in abstention

Recommendation #4: Public Health Impact of Implementing HBV Minipool NAT for Blood Donor Testing

Whereas, the hepatitis B virus (HBV) risk from transfusion now exceeds that from human immunodeficiency virus (HIV) and hepatitis C virus (HCV); and,

- HBV mini-pool nucleic acid testing (MP NAT) as currently configured has limited ability to reduce risk of transfusion transmitted HBV compared with individual donor (ID) NAT technology that is under development; and,

- The average morbidity of HBV infection is significantly less than that of HIV and HCV, but donor screening by MP NAT would incur a cost comparable to other NAT tests; and,

- Vaccination is an effective prevention strategy for HBV unlike HIV and HCV.

In regard to the introduction of mini-pool (as currently conceived) HBV NAT for blood donations, the Committee believes that for comparable expenditures of health care dollars the general public health would be better served by expanding the hepatitis B immunization program.

The Committee believes the Secretary should encourage the development of multiplex direct pathogen testing on individual donations.

Voting on August 27:
9 in favor
0 against
1 in abstention

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